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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/796,522

03/09/2004

Joseph F. Poduslo

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08/15/2006

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/796,522	<b>Applicant(s)</b> PODUSLO ET AL.	
	<b>Examiner</b> Olga N. Chernyshev	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-68 is/are pending in the application.
- 4a) Of the above claim(s) 47 and 51-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-34, 36-44, 49, 50, 67 and 68 is/are rejected.
- 7) ☒ Claim(s) 35, 45-46 and 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Response to Amendment***

1. Claim 31 has been amended and claims 67-68 have been added as requested in the amendment filed on July 26, 2006. Following the amendment, claims 31-68 are pending in the instant application.

Claims 47 and 51-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claims 31-46, 48-50 and 67-68 are under examination in the instant office action.

2. In response to Applicant's request at p. 7, section I with respect to claims 51-56, the Examiner acknowledges that if the generic claim 31 is found to be allowable, all species would be examined.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on July 26, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 102***

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6. Claims 31-34, 42 and 43, as amended, and new claims 67-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al., 1995 for those reasons of record as applied to claims 31-34, 42 and 43 in section 13 of Paper mailed on April 26, 2006.

Applicant traverses the rejection on the premises that the amendment to claim 31, which defines a non-A $\beta$  polypeptide as “a diagnostic or therapeutic agent for a disorder of the central nervous system (CNS)”, eliminates Saito as prior art because an OX26 monoclonal antibody used in Saito reference does not represent a diagnostic or therapeutic agent for CNS. Applicant’s arguments have been fully considered but are not persuasive for the following reasons.

At p. 6, line 8-9 of the instant specification it is stated: “A $\beta$  polypeptides can be linked to any non-A $\beta$  polypeptide, and in particular, to any polypeptide that is useful for diagnosis or treating a disorder of the CNS”. Thus, the specification encompasses any non-A $\beta$  polypeptides with a preference on those that are useful in diagnosis or treatment of CNS but with no exclusiveness to any particular ones. Thus, Saito et al. reference remains a proper prior art publication and, therefore, the instant rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

7. Claim 44 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al., 1995 for reasons of record in section 15 of Paper mailed on April 26, 2006.

Applicant argues that “Saito does not teach that the A $\beta$  polypeptide enhances transport across the blood brain barrier (BBB)” and further that “upon review of Saito, one skilled in the art would not be motivated to conjugate A $\beta$  to a diagnostic or therapeutic agent for CNS

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disorders” (pp. 10-11, section VI of the Response). Applicant’s arguments have been fully considered but are not persuasive for reasons that follow.

There appears to be no disagreement that the instant invention and research data disclosed in the article by Saito are predicated on the different approaches. However, the claim 44, as written, is directed to a composition comprising an A $\beta$  1-42 peptide linked to a non-A $\beta$  polypeptide, with no reference to mechanisms of transport across the BBB or better delivery systems. The Examiner maintains that because it is well known in the art that the two most common forms of A $\beta$  polypeptides are 1-40 and 1-42, therefore one skilled in the art would have been motivated to substitute A $\beta$  1-40 of Saito for A $\beta$  1-42 isoform, and that further that to use A $\beta$  1-42 isoform instead of A $\beta$  1-40 to construct a known chimeric peptide does not represent a novel inventive concept.

8. Claims 36-40 and 49-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. and further in view of Solomon et al., 1999 (WO 99/60024) for reasons of record in section 16 of Paper mailed on April 26, 2006.

Applicant traverses the instant rejection by arguing that Saito et al. reference does not disclose the claimed composition, similarly to the arguments as applied to claim 44 above. Applicant’s arguments have been fully considered but are not persuasive because, as fully explained earlier (see section 7 of the instant office action), the Examiner maintains that because the instant claims encompass a composition comprising a chimeric polypeptide and further in view of the decision in *In re Hyatt* (“During patent examination, the pending claims must be “given \*>their< broadest reasonable interpretation consistent with the specification.” *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the

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opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 51 (CCPA 1969)”), the only limitations that are considered relevant with respect to prior art analysis, are the limitations describing the structure of the claimed protein. Because Saito et al. reference teaches each and every element of the recited structure, the conditions for proper art rejection are met.

9. Claim 41 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. and further in view of US Patent 5,670,477, for reasons of record in section 17 of Paper mailed on April 26, 2006.

Similarly, Applicant’s reasoning that Saito et al. article does not disclose the claimed A $\beta$  polypeptide linked to an antibody is not persuasive (see explanations in sections 7-8 of the instant office action) and the instant rejection is maintained.

### ***Conclusion***

10. Claims 31-34, 36-44, 49-50 and 67-68 are rejected. Claims 35, 45-46 and 48 are objected to for being dependent on the rejected claim, but are considered free of prior art and potentially allowable if rewritten in independent form to include all the limitations of the base claims.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

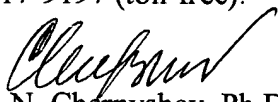
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

August 9, 2006